



## Post Authorisation Assessments

### Avishield IB H120, Lyophilisate for Oculonasal Suspension/Use in Drinking Water, for Chickens

•	05 August 2022	Unlimited Renewal
•	06 May 2022	Submission of an updated Ph. Eur. TSE certificate of suitability for a starting material from an already approved manufacturer. Changes to a test procedure (including replacement or addition) for the active substance.
•	12 January 2022	Deletion of a non-significant parameter of an active substance in the manufacturing process of the active substance. Changes to a test procedure for the active substance. Changes to a test procedure for the active substance. Deletion of a specification parameter of the finished product.
•	11 June 2021	Replacement to a test procedure for the finished product. Change in the specification limits of the finished product.
•	05 March 2020	Addition of a supplier of packaging components or devices. Deletion of a non-significant parameter of an active substance used in the manufacturing process of the active substance. Deletion of a supplier of a starting material.
•	11 February 2020	Change in the SPC, labelling or package leaflet due to new data.
•	17 May 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	02 April 2019	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS
•	26 March 2019	Addition of a supplier of packaging components.
•	30 October 2018	Change in RMS from UK to NL.
•	30 August 2018	Update to the labelling to add the local representative.
•	17 August 2018	Change in the local representative and distributor in Germany